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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,155	12/29/1998	HIROAKI TAKAYAMA	Q52816	5866

7590 06/10/2002  
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WASHINGTON, DC 200373202

EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/10/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/214,155

Applicant(s)

TAKAYAMA ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 3 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 3 and 4 are pending.

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Brief filed in paper no. 30 is hereby acknowledged. Finality of the rejection is withdrawn and rejections over Miyamoto are withdrawn in view of declaration. New rejections are as follows.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is intended by derivative in claims 3 and 4. Deletion of this term is suggested.

There is insufficient antecedent basis for this limitation in the claim. See claim 3 which does not contain all the compound as claimed in 4. See R4 and R3 when they are not H.

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***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (US 5,945,410) and (US 6,306,844). Both the references teach 2-methyl and 2-alkyl 19-nor 20(S) vitamin D<sub>3</sub>. See the entire documents especially fig. 1 and 2 and examples 1; lines 36-67, in col. 15 and lines 1-37 in col. 16 in '410; formula 1 and lines 1-19 and 45-67, col. 2; cols. 5 and 6 and Table 1 in US '844.

**1. Determining the scope and contents of the prior art.**

Prior art US '410 teach 1a, 25-dihydroxy-2a and 1a, 25-dihydroxy-2beta methyl 19-nor vitamin D<sub>3</sub> (compound 12 and 13, example 1). See biological activity of 2-methyl substituted 19-nor 1,25-(OH)<sub>2</sub>D<sub>3</sub> compounds and their 20-S isomers. See lines 36-67, in col. 15 and lines 1-37 in col. 16 where 2-methyl substitutions produced surprisingly potent compounds see Table 1.

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Prior art '844 discloses 19-nor 20-S compound are shown to be more potent as compared to 1,25(OH)<sub>2</sub>D<sub>3</sub> on HL-60 differentiation, which is useful for the treatment of psoriasis and cancer, especially against leukemia, colon cancer, breast cancer and prostate cancer. See cols. 5 and 6 and Table 1.

**2. Ascertaining the differences between the prior art and the claims at issue.**

The prior art of record is drawn to structurally similar compounds, which differ, from the compounds embraced by the instant claims in that they are homologs.

*In the instant case prior art compound does not contain a methylene group at 19-position, i.e. these are 19-nor, 20-S vitamin D<sub>3</sub> compounds whereas instant invention is drawn to 20-S vitamin D<sub>3</sub> compounds. The difference is one additional carbon at 19-position of the ring.*

The skilled artisan would have been motivated to modify the teaching of the prior art to prepare homologs because it is recognized in the art that homologs are structurally similar and would be expected to possess similar properties. *Ex parte Henze* (POBA 1948) 83 USPQ 167 .

**3. Resolving the level of ordinary skill in the pertinent art.**

Compounds that differ only by the presence of an extra methyl group are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue.

The homologue is expected to be prepareable by the same method and to have the same properties i.e. useful for cell differentiation.

**4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions about similar properties and similar methods of preparation are rebuttable but initially, the homologues are obvious even in the absence of a specific teaching to methylate, *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druey* 138 USPQ 39.

In all of these cases, the close structural similarity of two compounds differing by only one (or two) methyl groups sufficed; no specific teaching to methylate was present or required.

2. Claim 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Trost M. Barry et al. The reference teaches a palladium-catalyzed alkylative cyclization of enynes for the synthesis of vitamin D derivatives for the same reasons set forth in our previous office actions. .

The instant claims differ from the reference by employing an analogous starting material which differs in having a methyl group at 4-position of the compound of formula III i.e. in instant claims 4-position is substituted by a methyl group whereas prior art teaches no substituents at this position.

The starting materials are analogous in that they are both are belong to enynes of formula III.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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June 1, 2002



SABIHA QAZI, PH.D  
PRIMARY EXAMINER